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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/611,414

06/30/2003

David P. Holden

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05/31/2006

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APPLIED BIOSYSTEMS
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EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,414

Applicant(s)

HOLDEN ET AL.

Examiner

Jason M. Sims

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to a method for allelic classification involving acquiring intensity information for a plurality of samples and applying the likelihood model to each of the samples, classified in class 702, subclass 20.
- II. Claims 22-33 and 59-65, drawn to a method for clustering analysis involving identifying a sample set comprising a plurality of data points and identifying discrete clusters representing a homozygous allelic classification and performing mutational analysis along with a computer system capable of carrying out the involved method steps, classified in class 702, subclass 20.
- III. Claims 34-41 and 66-68, drawn to a method for allelic classification involving identifying a sample set comprising a plurality of data points and performing a confidence value assessment for each data point and a computer system capable of carrying out the involved method steps, classified in class 702, subclass 20.
- IV. Claims 42-58, drawn to a computer readable medium having stored thereon instructions which can perform acquiring experimental information from a plurality of samples following reacting each sample using a dual-label amplification protocol wherein the protocol comprises a Taqman or SNPLEX protocol, classified in class 702, subclass 20.

- V. Claims 69-79, drawn to a computer-based system for performing allelic classification involving a database for storing experimental information and retrieving the information and normalizing the information, classified in class 702, subclass 20.
- VI. Claims 80-83, drawn to a computer-based system for performing allelic classification involving a database for storing experimental information for a plurality of samples, identifying a sample set and applying the likelihood model to the data points, classified in class 702, subclass 20.

Inventions I-VI are directed to related subject matter of analyzing experimental information involving intensity data points. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, group I is drawn to a method for allelic classification involving acquiring intensity information for a plurality of samples and applying the likelihood model to each of the samples. Group II is drawn to a method for clustering analysis involving identifying a sample set comprising a plurality of data points and identifying discrete clusters representing a homozygous allelic classification and performing mutational analysis along with a computer system capable of carrying out the involved method steps. Group III is drawn to a method for allelic classification involving identifying a sample set comprising a plurality of data points and performing a confidence value assessment for each data

point and a computer system capable of carrying out the involved method steps. Group IV is drawn to a computer readable medium having stored thereon instructions which can perform acquiring experimental information from a plurality of samples following reacting each sample using a dual-label amplification protocol wherein the protocol comprises a Taqman or SNPLEX protocol. Group V is drawn to a computer-based system for performing allelic classification involving a database for storing experimental information and retrieving the information and normalizing the information. Group VI is drawn to a computer-based system for performing allelic classification involving a database for storing experimental information for a plurality of samples, identifying a sample set and applying the likelihood model to the data points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

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Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)-272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 30 May 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER